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All Interested Parties:

The Massachusetts Department of Public Health (MDPH) and the Massachusetts Emergency Management Agency (MEMA) have requested a supply of potassium iodide (KI) from the Nuclear Regulatory Commission (NRC) and have developed a plan for pre-distribution of some of the KI to individuals and schools within the three 10-mile Emergency Planning Zones (EPZs) that impact upon Massachusetts communities. In discussions with various individuals concerning the pre-distribution of KI to the public, a number of questions have arisen concerning dosages of KI that are appropriate for various age groups. The purpose of this letter is to clarify the Food and Drug Administration's (FDA) guidance and the MDPH's support of this guidance concerning appropriate KI dosages.

Regarding the dosage of KI for children, the only currently available, FDA-approved over-the-counter formulation is a 130 mg tablet. This is the recommended dose for adults and for adolescents approaching adult size (≥ 70 kg), and was the dose recommended until recently for all persons one year of age or older. However, in December 2001 FDA made revised recommendations regarding the lowest effective dose, namely 16 mg under age 1 month, 32 mg for age 1 month to 3 years, and 65 mg for age 3 years to 18 years.

Until the 65 mg tablet is available in an FDA-approved formulation, MDPH supports the administration of the 130 mg tablet for children in settings such as schools or child care centers in the event of emergencies. This is in agreement with FDA statements. This dose is safe and well within the recommended therapeutic range of KI for other indications. The blocking effect of iodide on the thyroid lasts only a few days (daily dosing is needed as long as the child is exposed to the radioiodine) and any suppressive effect of KI on thyroid function has been shown to be minimal, even in young children.

The logistics of providing KI to persons too young to take pills are more complicated. KI pills can be crushed and dissolved in small amounts of juice or formula. For instance, if a 130 mg tablet were dissolved in 8 ounces of liquid, one ounce would contain 16 mg of KI. The FDA has noted that absolute precision in dosing is generally not critical to safety or efficacy, and has emphasized in their guidance document that across populations at risk for radioiodine exposure, the overall benefits of KI far exceed the risks of overdosing, especially in children.

I hope that the above information will be useful to the pharmacies, town offices, and school personnel who are assisting in the pre-distribution process as well as to individuals that will be receiving the KI through this process. Additional information concerning KI is available on the Radiation Control Program's Web Site at www.state.ma.us/dph/rcp or by calling the Radiation Control Program at 617-727-6214.

Sincerely,

Howard K. Koh

Howard K. Koh, MD, MPH
Commissioner